Instructions for Use for Medartis MODUS Systems

I. General Instructions

These instructions for use do not include all of the information necessary for use of the products. Additional information on the products (e.g. surgical techniques, instructions for handling of sterile products, instructions for reprocessing and maintenance, assembly/disassembly instructions) can be found on the internet at www.medartis.com/documentation/instructions-for-use. They can also be requested from your local Medartis territory consultant or distribution partner. All instructions provided in this document and in the corresponding user information must be followed.

The individual parts of the system may only be accepted when the manufacturer's label and packaging are undamaged and unopened at the time of delivery. If this is not the case, the rejected goods must be returned to Medartis AG, Basel/Switzerland or to the relevant Medartis territory consultant or distribution partner within ten working days.

II. Scope

Implants and instruments for the following MODUS systems are covered by these instruction for use:

- MODUS Midface
- MODUS Condylar Head Fracture System
- MODUS Bone Fixation System

The complete list of items can be found in the corresponding surgical technique(s) under www.medartis.com/documentation/instructions-for-use.

III. Product Description

Product Materials

Medartis implants and instruments are manufactured from biocompatible materials. All materials are standard implant and instrument materials for use in medical devices for orthopedics, traumatology, and general surgery.

Product	Material
Plates	Pure titanium, titanium alloy
Screws	Pure titanium, titanium alloy
Instruments	Stainless steel, PEEK, aluminum, Nitinol, silicone or titanium
Containers	Stainless steel, aluminum, PEEK, polyphenylsulfone, polyurethane, silicone

Color Coding Concept

MODUS instruments are color coded according to the diameter of the screws being used:

System Size	Color Code
0.9/1.2	Red
1.5/1.8	Green

MODUS plates and screws have their own color, corresponding to a specific implant technology:

Implant plates gold	Fixation plates (fixation)
Implant screws gold	Cortical screws (fixation)
Implant screws green	SpeedTip screws (self-drilling)

Intended Purpose

The MODUS fixation systems are intended for use in oral and maxillofacial surgery.

Indications and Contraindications

Indications and contraindications for each MODUS System can be found in the corresponding surgical technique under www.medartis.com/documentation/instructions-for-use.

Intended User / Patient Target Group

The products may only be used by health care professionals, e.g. surgeons, radiologists, operating room staff, and individuals involved in preparation of the device, who hold the relevant qualifications.
Medartis, as the manufacturer, recommends that the user reads all available documents (e.g. surgical techniques, instructions for handling of sterile products, instructions for reprocessing and maintenance, assembly/disassembly instructions) before first use and contacts other users who have practical experience with this type of treatment. The user must be familiar with the state of the art and the instrument and implant function.
For specific patient target groups related to each system refer to the corresponding surgical technique of the system being used. Responsibility for proper selection of patients rests with the surgeon, based on the specific indications and contraindications of each system and on patient-related factors (e.g. activity, occupation, mental health, age, bone quality).

Intended Performance

The available clinical data confirms good clinical performance and safety outcomes in a wide range of indications of the MODUS systems, when they are used according to the user information. This is in line with or superior to the state of the art.

IV. Side Effects / Possible Complications

In most cases, potential complications have a clinical or patient-related source as opposed to arising from the implants/instruments. These include among other things:

- Loosening of the implant from insufficient fixation
- Hypersensitivity to metal or allergic reactions
- Bone necrosis, osteoporosis, insufficient revascularization, bone resorption and poor bone formation that can cause premature loss of fixation or implant breakage
- Soft tissue irritation and/or nerve damage through surgical trauma
- Early or late infection, both superficial and deep
- Elevated fibrotic tissue reaction around the surgical area
- Complications in implant removal from improper explantation of the implant (e.g. due to bony ingrowth)

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, or incorrectly combined implant components.

V. Warnings

- The products may only be used by medical personnel who hold relevant qualifications.
- Medartis, as manufacturer, recommends that the user reads all available documents before first use and contacts other users who have practical experience with this type of treatment.
- All of the implant components are intended for single use and may not be reused under any circumstances. Unless otherwise expressly stated on the label, the instruments can be reused.
- Necessary care must be observed for storage and use of the products:
  - Damages (e.g. from improper cutting or bending) to and/or scratches on the instruments/implants can substantially impair the strength of the product and lead to premature breakage.
  - Repeatedly bending the plate in opposite directions may cause the plate to break during postoperative treatment.
- Twist drills: It is recommended not to exceed a maximum drilling speed of 1'000 revolutions per minute to avoid overheating the bone. The drill guide and bone should be cooled while drilling. Reusable, non-sterile packaged twist drills may only be used for a maximum of ten times.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way!
- The sterilizing cases, instrument trays and implant containers shall not be vigorously shaken or tipped over since the individual components and content may become damaged or fall out.
- Compatibility information: MODUS 2 implants and instruments are not compatible with other MODUS systems in terms of color concept.

For application-specific warnings related to MODUS systems, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use) of the corresponding product system being used.

VI. Cautions

- All of the system components have been developed and manufactured for a specific purpose and are therefore precisely adapted to each other. The user may not alter any of the components or replace them with an instrument or product from another manufacturer even if the size or shape is similar or exactly corresponds to that of the original product. The use of materials from other manufacturers, structural changes resulting from the use of third-party products and/or material impurities, as well as minor deviations or imprecise fit between the implants and instruments, or similar, can represent a risk for the user, patient or third parties.
- Use the indicated screwdriver for the respective system size. Make sure that the screwdriver/screw head connection is precisely aligned in axial direction. If not, there is a greater risk of damage to the implant and screwdriver blade. When inserting the screw, ensure that a sufficient axial force is used between blade and screw. At the same time, the axial force should be in certain limits in order not to damage the bone structure.

For application-specific cautions related to MODUS systems, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use) of the corresponding product system being used.

VII. General Important Information

Clinical Benefits

In consideration of patient's clinical condition and medical history, the treating physician shall ensure that the use of MODUS systems can be justified based on a patient-specific benefit/risk assessment. Based on the clinical evaluation and risk analysis, all residual risks are deemed acceptable when weighed against the benefits to the patient based on current knowledge/the state of the art.

Selecting the Appropriate Implants

Medartis, as the manufacturer, does not recommend a specific surgical procedure for a specific patient. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case. The follow-up treatment as well as the decision of whether to retain or explant the implant is the responsibility of the user.
The treating physician must beforehand become thoroughly familiarized with the procedure, for example by:

- Carefully studying all the product documentation
- Carefully reviewing the current professional literature
- Consulting with colleagues experienced in this field and with the use of this system
- Practice in handling the system, practice of the surgical procedure and postoperative treatment

Generally, implants are designed to remain in the body temporarily and be removed after sufficient (osseous) healing has taken place. They are not designed for long-term bone replacement. Where they are mechanically supporting the osteosynthesis, the regular operating period of the implants is expected to be between 30 days and 6 months.

Removal of Implants

In the case of complications, it might be necessary to remove the implants. For removal use the indicated screwdriver. Make sure that the screwdriver/screw head connection is precisely aligned in axial direction.

Postoperative Care

Taking into account the individual fracture conditions and patient compliance, it is important to ensure adequate postoperative relief of the osteosynthesis in terms of adaptation or mobilization stability (e.g. splinting and/or immobilization). Postoperatively, the fixation achieved with the implants must be treated with care until the bone has fully healed. Patients must strictly observe follow-up instructions given by their physicians to avoid detrimental strain on the implants. Early load bearing can increase the risk of loosening, migration or breakage of the implants

Information on MR-Marking

Conditionally MR safe

Non-clinical tests under worst case conditions show that all Medartis implants are MR conditional.

Magnetically Induced Torque and Displacement According to ASTM F2213-06 and ASTM F2052-06e1
Non-clinical tests in a 3T MRI system under worst conditions have shown that no relevant torque and displacement of Medartis products were observed at a maximum spatial gradient of 12 T/m.

Image Artifacts According to ASTM F2119-07
Non-clinical tests in a 1.5T MRI system showed image artifacts extending up to 29 mm away from the implant during a gradient echo pulse sequence.

Radio-Frequency Induced Heating According to ASTM F2182-11a
Electromagnetic and thermal simulations combined with non-clinical tests demonstrated maximum temperature rises of 13.1°C (1.5 T) and 4.2°C (3 T) after 15 minutes of continuous scanning (Normal Operating Mode, whole body specific absorption rate (SAR) of 2.1 W/kg).

Since the above test results were obtained through non-clinical tests, the actual in vivo temperature increase will depend on a variety of factors beyond the SAR and scan duration. Therefore, note the following:

- Do not scan patients with impaired thermo regulation, temperature or pain sensation.
- Reduce the SAR as much as possible as reducing the SAR strongly reduces the temperature increase caused by RF heating.
- Use an external cooling/ventilation system to help reduce the body temperature.

VIII. Cleaning, Disinfection and Sterilization of Non-Sterile Products

All implants and instruments in the MODUS systems that are delivered **NON-STERILE** must be cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery. All packaging must be removed before preparation.
Thorough cleaning and disinfection are essential for effective sterilization.
All implant components are intended for one single application in a single patient. Implants that were used in a patient and removed, have to be discarded following the local requirements. Application of an already used device may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, application of an implant that has already been used may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury of the patient or user.
Implants that have not come into direct contact with a patient may be reprocessed. Implants that have come into direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately before they can be placed back into the implant container/tray.
It is your responsibility to ensure that the implants are completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained for each cycle.
The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.

Detailed instructions for processing/reprocessing of medical devices are described in the brochure “Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products” and can be downloaded from www.medartis.com/documentation/instructions-for-use.

IX. Complaints and Adverse Events

Any complaint or adverse event that has occurred in relation to the device should be reported to the manufacturer and the respective national competent authority of the state in which the user and/or patient is established.

X. References

The following user documentation on the products is additionally available online and can be found under the following link www.medartis.com/documentation/instructions-for-use:
- Surgical techniques
- Instructions for handling of sterile plates, screws, staples and instruments
- Instructions for cleaning, disinfection, sterilization, inspection and maintenance
- Assembly/disassembly instructions

For additional information contact your local Medartis territory consultant, distribution partner or the manufacturer directly under the given address.

XI. Symbols

	Consult instructions for use
	Article number / Reference number
	Lot number / Batch code
	Serial number
	Non-sterile
	Single-use product. Do not reuse The product is intended for one single application in a single patient. Application of an already used product may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.
	Do not use if packaging is damaged
	Medical device
 YYYY-MM-DD	Manufacturer Date of manufacture
	Conditionally MR safe
	Authorized representative in the European Community / European Union
	Importer
	HexaDrive
	Self-drilling screws
	Applies only to EC risk class I devices in sterile condition, I devices with a measuring function, I reusable surgical instruments, IIa and IIb devices.
	Applies only to EC risk class I devices.

This document is subject to continuous revision. The most current version is always available online at www.medartis.com/documentation/instructions-for-use.

Medartis AG
Hochbergerstrasse 60E
4057 Basel/Switzerland
Phone +41 61 633 34 34
Fax +41 61 633 34 00
info@medartis.com
www.medartis.com

Importer EU
Medartis GmbH
Am Gansacker 10
79224 Umkirch/Germany

Medartis GmbH
Am Gansacker 10
79224 Umkirch/Germany

Sponsor Details Australia & New Zealand:
Medartis Australia & New Zealand Pty Ltd.
64 Brooks Street
Fortitude Valley QLD, 4006

Disclaimer: This information is intended to demonstrate the Medartis portfolio of medical devices. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. Medartis is not giving any medical advice.
The devices may not be available in all countries due to registration and/or medical practices. For further questions, please contact your Medartis representative (www.medartis.com). This information contains CE-marked products.
For US only: Federal law restricts this device to sale by or on the order of a physician.

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